

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appln. Of: NITZ et al.

Serial No.: 10/524,162

Filed: June 17, 2005

For: COMPOUNDS, COMPOSITIONS AND METHODS...

Examiner: Kosack, Joseph R.

Group: 1626

DOCKET: MICRODOSE 09.06

Confirmation No. 2828

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132
DECLARATION OF ROBERT O. COOK, PhD

Dear Sirs:

The undersigned states as follows:

(1) My name is Robert Cook. I am Senior Director, Product Commercialization, of Microdose Therapeutx, Inc., the assignee of the above identified patent application. My curriculum vitae is attached hereto as Exhibit A.

(2) In my capacity as Senior Director, Product Commercialization of Microdose Therapeutx, Inc. (my company), I have access to the patent application files and research and development files of my company.

(3) I am familiar with the prosecution of the above identified US Patent Application. I understand the Examiner has taken the position that the test data in the application does not demonstrate that the compound of claim 36 is effective in preventing pneumovirus infection.

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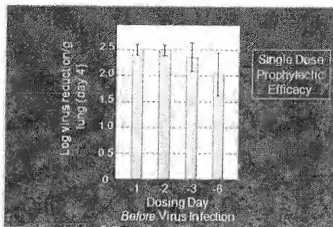
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(4) I reviewed the research files of my company for tests demonstrating prophylactic activity of the compound of claim 36, which compound is designated in the report below as "MDT-17470", and provide experimental tests I found in my company's records as follows:

Example

Administration of a 12 mcg aerosol dose of MDT-17470 6 days, 3 days, 2 days and 1 days prior to RSV infection was shown to maintain a ≥ 2 log reduction in RSV (antiviral effect) in the cotton rat model of RSV infection (Figure 1). This data supports the prophylactic use of MDT-17470 and its analogues.

Figure 1: Effect of time of dosing for MDT-17470 prior to RSV infection, at day 4 post-infection in the prophylaxis model of RSV infection in the cotton rat.




(5) As can be seen administration of the claimed compound (designated as MDT-17470) prior to pneumovirus (RSV) infection provides a prophylactic effect. Thus, I consider

administration of MDT-17470, i.e. the compound claimed in claim 38 to provide prophylactic effect against pneumovirus infection.

I hereby declare that all statements made hereof of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issued thereon.

Date: 13 Dec 2010

By: 
Robert O. Cook

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